



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0762; FRL-10019-62]

Trifludimoxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trifludimoxazin in or on multiple commodities which are identified and discussed later in this document. BASF corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0762, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide

remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-

OPP-2018-0762 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0762, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of April 19, 2019 (84 FR 16430) (FRL-9991-14), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F8709) by BASF corporation, 26 Davis Drive, PO Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide trifludimoxazin, in or on almond, hulls at

0.15 parts per million (ppm); fruit, citrus, group 10-10 at 0.01 ppm; fruit, pome, group 11-10 at 0.01 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice) at 0.01 ppm; grain, cereal, group 15 at 0.01 ppm; nut, tree, group 14-12 at 0.01 ppm; peanut at 0.01 ppm; peanut, hay at 0.01 ppm; vegetable, foliage of legume, group 07 at 0.01 ppm; vegetable, legume, group 06 at 0.01 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trifludimoxazin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifludimoxazin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The available database of guideline studies for trifludimoxazin indicates that the primary target organs are the thyroid and liver. Trifludimoxazin is a protoporphyrinogen oxidase (PPO)-inhibitor. PPO is a key enzyme in chlorophyll and cytochrome pigments, as well as in heme. Although hematological effects associated with this class were observed, they are not considered adverse at the selected lowest-observable adverse-effects levels (LOAELs). Effects on the thyroid occurred in rats and consisted primarily of follicular cell hypertrophy/hyperplasia and altered colloid of the thyroid after subchronic and chronic exposure durations. Increased relative thyroid weights were also observed in male rats; however, thyroid hormones were not adversely affected after subchronic exposure for males and females. Liver effects (increased alanine aminotransferase (ALT) and alkaline phosphatase (ALP), organ weight, and histopathology) were also observed at the same dose as thyroid effects in male rats after subchronic exposure. In mice, increased liver weight, increased γ -glutamyl transferase (GGT), and hypertrophy were observed after subchronic exposures. Increased liver weight, foci of (eosinophilic) cellular alteration, centrilobular hypertrophy, macrovesicular fatty change and centrilobular pigment storage was observed in male mice and oval cell hyperplasia and (multi)focal necrosis was observed in female mice after chronic exposure. After chronic exposure to the rat, increased pigment, multinucleated hepatocytes, and bile duct hyperplasia in the liver was observed at the same dose as thyroid effects. Effects on the reproductive system were observed as evidence of increased abnormal sperm in male rats in the extended one generation reproductive toxicity study (EOGRTS), and as effects to the epididymis in rats after subchronic and chronic exposure.

Trifludimoxazin did not demonstrate neurotoxic potential in either acute or subchronic neurotoxicity studies in rats. Observations suggestive of neurotoxicity were seen in the 90-day

subchronic study in dogs (e.g., functional observational battery (FOB) deficits, histopathological findings in the spinal cord and medulla oblongata (degeneration of fasciculus gracilis and white matter)), but no neurotoxicity effects were seen in either the 28-day dog study, which tested lower doses, or the chronic dog study, which tested higher doses relative to the 90-day study.

There were no adverse maternal or developmental effects observed in the rat developmental toxicity study at the limit dose. However, in the rabbit developmental study, decreased fetal body weight was observed at a lower dose than maternal toxicity (increased incidence of late abortions); thus, increased quantitative susceptibility was observed. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) in rats demonstrated no increase in susceptibility as no effects were observed in the offspring while increased incidence and severity of follicular cell hypertrophy/hyperplasia and altered colloid in the thyroid was observed in the parental animals.

Immunotoxicity was not observed throughout the toxicity database. Additionally, there were no effects in the dermal toxicity study, including any effects to the thyroid.

The Agency has classified trifludimoxazin as “suggestive evidence of carcinogenic potential” based on thyroid tumors, driven by adenomas, observed in male rats at 750 ppm (33 mg/kg/day); an absence of treatment-related tumors in female rats and in male and female mice, and a lack of concern for mutagenicity. The Agency has concluded that quantification of cancer risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including potential carcinogenicity, that could result from exposure to trifludimoxazin. The chronic reference dose (0.11 mg/kg/day) is several times lower than the level at which tumors were observed.

Specific information on the studies received and the nature of the adverse effects caused by trifludimoxazin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in pages 13-19 of document Trifludimoxazin: New Active Ingredient Human Health Risk Assessment for Registrations on Legume Vegetable Group 6, Foliage of

Legume Vegetable Group 7, Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Tree Nut Group 14-12, Cereal Grain Group 15 (except rice), Forage Fodder and Straw of Cereal Grain Group 16 (except rice), Peanut and Peanut Hay (hereinafter “Trifludimoxazin Human Health Risk Assessment”) in docket ID number EPA-HQ-OPP-2018-0762.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

A summary of the toxicological endpoints for trifludimoxazin used for human risk assessment can be found in the Trifludimoxazin Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to trifludimoxazin, EPA considered exposure under the petitioned-for trifludimoxazin tolerances in 40 CFR part 180. EPA assessed dietary exposures from trifludimoxazin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for trifludimoxazin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined chronic dietary exposure assessment using tolerance-level residues, 100 percent crop treated (PCT), and default processing factors.

iii. *Cancer.* Based on the Agency's analysis of the available data, EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to trifludimoxazin. Quantification of cancer risk using a non-linear RfD approach will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to trifludimoxazin; therefore, a separate cancer dietary assessment was not conducted.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for trifludimoxazin. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trifludimoxazin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trifludimoxazin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Using the Pesticides in Water Calculator (PWC), Pesticide Root Zone Model and the Varying Volume Water Model (PRZM/VVWM), EPA calculated the estimated drinking water concentrations (EDWCs) of trifludimoxazin for acute and chronic exposures in surface and ground water. EPA used the modeled EDWCs directly in dietary exposure model to account for the contribution of trifludimoxazin residues in drinking water as follows: 5.0 ppb was used in acute dietary assessment and 3.6 ppb was used in chronic dietary risk assessment.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Trifludimoxazin is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

The Agency has not found trifludimoxazin to share a common mechanism of toxicity with any other substances, and trifludimoxazin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trifludimoxazin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account

for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was evidence of quantitative pre-natal susceptibility in the rabbit developmental toxicity study. However, the degree of concern is low because clear NOAELs were identified for the effects, and the selected endpoints and doses are protective of the observed developmental effects and observed susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for trifludimoxazin is complete.
- ii. Although there was evidence for neurotoxicity in the 90-day subchronic dog study, the degree of concern for the toxicity is low because this study is used as the basis for the risk assessment PODs and is protective of any potential neurotoxicity.
- iii. Clear NOAELs were identified for the developmental/offspring effects observed in the rat and rabbit prenatal developmental studies, and endpoints selected for risk assessment are protective of these effects and the quantitative susceptibility observed in the rabbit developmental study and rat EOGRTS.
- iv. There is no concern due to any residual uncertainties in the exposure database. No data gaps were identified, and exposure estimates are based upon conservative default assumptions. Tolerance-level residues and 100PCT are used in dietary exposure assessments, and residential exposures are not anticipated from the proposed use pattern. As such, residual uncertainty is negligible and does not impact considerations for the FQPA Safety Factor. EPA made conservative (protective) assumptions in the ground and surface water modeling used to

assess exposure to trifludimoxazin in drinking water. These assessments will not underestimate the exposure and risks posed by trifludimoxazin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, trifludimoxazin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that the chronic risk estimates of food and drinking water for trifludimoxazin are below the Agency's LOC at < 1% of the cPAD for the United States population and all population subgroups. There are no residential uses for trifludimoxazin.

3. *Short-term risk and Intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term and intermediate-term adverse effect was identified; however, trifludimoxazin is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term and intermediate-term risk is assessed based on short-term or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term

risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for trifludimoxazin.

4. *Aggregate cancer risk for U.S. population.* As indicated above, the Agency has determined that the non-cancer chronic dietary assessment would account for any dietary cancer risks. Based on the level of chronic risk being below the Agency's level of concern, EPA concludes aggregate exposure to trifludimoxazin will not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to trifludimoxazin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High-Performance Liquid Chromatography with tandem Mass Spectroscopy (HPLC-MS/MS) method (Method D147/02 in plant matrices)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Trifludimoxazin is a new active ingredient, and no maximum residue limits (MRLs) have yet been established by Codex.

C. Response to Comments

One commenter expressed concern about the release of pesticide chemicals to the environment. The FFDCA does not authorize EPA to consider risks to the environment, per se; rather, the FFDCA authorizes EPA to establish tolerances that permit certain levels of pesticide residues in or on food when the Agency can determine that such tolerances are safe. Taking into consideration the factors required in the FFDCA, EPA has made that safety determination for the tolerances subject to this action; the commenter provided no information relevant to that conclusion.

D. Revisions to Petitioned-For Tolerances

Based upon review of submitted data, the Agency is establishing tolerances that vary from what the petitioner requested. The petitioner had requested to establish tolerance on the entire cereal crop groups 15 and 16; however, the Agency has determined that the petitioned tolerance for cereal crop groups 15 and 16 must be revised to exclude rice commodities. While there are no data gaps for human health, the Agency has insufficient environmental fate data to support a tolerance on rice; therefore, the request to allow use on rice on the trifludimoxazin label will not be granted at this time. Because the product will not be used on rice, tolerances are not needed for residues in or on rice. Consequently, EPA is excluding rice from the tolerances being set on cereal crop groups 15 and 16.

V. Conclusion

Therefore, tolerances are established for residues of trifludimoxazin in or on almond, hulls; fruit, citrus, group 10-10; fruit, pome, group 11-10; grain, cereal, forage, fodder and straw, group 16 (except rice) ; grain, cereal, group 15 (except rice); nut, tree, group 14-12; peanut; peanut, hay; vegetable, foliage of legume, group 07 and vegetable, legume, group 06.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled

“Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 5, 2021.

Edward Messina,

Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.717 to subpart C to read as follows:

§ 180.717 Trifludimoxazin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide trifludimoxazin, including its metabolites and degradates, in or on the commodities to Table 1 of this section. Compliance with the tolerance levels specified in Table 1 is to be determined by measuring only trifludimoxazin, dihydro-1,5-dimethyl-6-thioxo-3-[2,2,7-trifluoro-3,4-dihydro-3-oxo-4-(2-propyn-1-yl)-2H-1,4-benzoxazin-6-yl]-1,3,5-triazine-2,4(1H,3H)-dione, in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
Almond, hulls	0.15
Fruit, citrus, group 10-10	0.01
Fruit, pome, group 11-10	0.01
Grain, cereal, forage, fodder, and straw, Group 16, except rice	0.01
Grain, cereal, group 15, except rice	0.01
Nut, tree, group 14-12	0.01
Peanut	0.01
Peanut, hay	0.01
Vegetable, legume, group 6	0.01
Vegetable, foliage of legume, group 7	0.01

(b) – (d) [Reserved]